Brief Summary of the Circulatory System Devices Panel Meeting – October 9, 2014

Introduction:

The Circulatory System Devices Panel of the Medical Devices Advisory Committee to the Food and Drug Administration met on October 9, 2014 to make recommendations regarding the classification of more-than-minimally manipulated allograft heart valves (MMM Allograft HVs). A MMM Allograft HV is a human valve or valved conduit that has been aseptically recovered from qualified donors, dissected free from the human heart, and then subjected to a manufacturing process(es) that alters the original relevant characteristics of the tissue. FDA is seeking committee input on the safety and effectiveness of MMM Allograft HVs and the regulatory classification for MMM Allograft HVs. MMM Allograft HVs are indicated for the replacement of diseased, damaged, malformed, or malfunctioning native or prosthetic valves.

Panel Deliberations/FDA Questions:

The panel discussed the list of risks provided by the FDA and agreed that the list was acceptable, except to note that hemorrhage may be procedurally related. Additionally, when the valves are used as a conduit, aneurysmal dilation with a true or false lumen may occur. Also, conduit rupture resulting from interventions such as balloon angioplasty or transcatheter valve placement in the conduit could be a potential risk which could cause death.

The panel unanimously agreed with the statement that the device type is life supporting.

The panel mostly agreed with the assessment that insufficient information exists to determine that general and special controls are sufficient to provide reasonable assurance of the safety and effectiveness of MMM allograft heart valves. Those who disagreed based their decision on the fact that few problems have been seen with the current device on the market. The main concern raised by the rest of the panel was the potential lack of oversight if new companies with different processing techniques were to enter the market.

The panel was asked to weigh in on whether the MMM allograft devices should be classified Class III. Twelve panel members agreed that the devices should be Class III and four believed they should be Class II.

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